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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,531	01/07/2002	Robert Frigg	8932-591	4875
20582	7590	07/14/2004	EXAMINER	
JONES DAY 51 Louisiana Aveue, N.W WASHINGTON, DC 20001-2113			COMSTOCK, DAVID C	
			ART UNIT	PAPER NUMBER
			3732	
DATE MAILED: 07/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/036,531	Applicant(s) FRIGG ET AL.	
	Examiner David Comstock	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-65 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☒ Claim(s) 43-61 is/are allowed.
 6) ☒ Claim(s) 1-6, 9-42 and 62-65 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 07 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11, 12, 15-17, 19-22, 24-31, 34-36, 38, 39, 41, 42 and 62-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowery et al. (5,364,399).

Lowery discloses a fixation device comprising a bone fastener 30 and a receiving member 20 (see Figs. 4-6). The bone fastener has a generally semispherical, convex head 32 that includes an outer collar, i.e. that portion of the head extending radially past the diameter of the unthreaded shank. The collar includes a top portion, immediately adjacent to a tool receiving portion 35 and indicated in Fig. 5 as reference numeral 33. The collar includes three lower portions, 33a, 34 and the annular lower portion connecting lower portions 33a and 34 (see Fig. 5). The lower portions define two concentric edges in the form of a ring, i.e. circular (these edges are seen in Fig. 5 as the line between the lower portion 33a and the annular lower portion and as the line between the annular lower portion and the lower portion 34, respectively). The lower edge defines a lower contour of a disk-shaped element, i.e. the head in its entirety. The lower contour defines a radial extent of a convex plane bearing surface. The edges abut the cylindrical portion in some positions (see Figs. 5 and 6). An imaginary convex,

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spherical surface can simultaneously pass through both edges. The fastener head is integrally formed with the shank. The receiving member includes a first portion 27 of substantially constant diameter and a second substantially concave portion 28 (see Fig. 4). The fastener is disposed about its own longitudinal axis, and a bore in the receiving member is disposed about a central axis, e.g. an axis extending vertically through the hole, as seen in Fig. 5, and the fastener is positionable so that the longitudinal axis is transverse to, i.e. oriented crosswise or laterally to and not parallel to, the central axis when the collar of the fastener abuts the inner surface of the bore (see Figs. 5 and 6). The collar has a constant diameter about the annular lower portion. A clamping member 40 locks the fastener with respect to the receiving member in a fixed configuration. The clamping member can be considered a grub screw since no specific, limiting definition is provided and the term is subject to varying interpretations. The clamping member can be released from the receiving member by unthreading it therefrom. The receiving member constitutes a longitudinal support 85 and comprises a channel, e.g. 86, that extends transverse, i.e. crosswise or laterally to, to a central axis of the bore (see Fig. 9). The channel is capable of receiving some longitudinal support (e.g. a longitudinal support could be inserted into the opening of the channel). With regard to claims 25 and 42, it is noted that the claimed "a longitudinal support" does not necessarily need to be the same longitudinal support referred to in the previous respective claim 24 and 41, i.e. "a" modifies "longitudinal support" instead of, for example, --the-- or --said--, which would force the longitudinal support to be interpreted as the same element.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10, 13, 14, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowery et al. (5,364,399).

Lowery discloses the claimed invention except for the ratio of half the diameter of the first portion to the radius of curvature of the concave portion between about 0.5 and about 1.0 or between about 0.85 and about 0.95; the collar diameter between about 4 mm and about 10 mm; and a collar thickness defined between the top portion and the lowest of the lower portions between about 0.5 mm and about 2 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device with dimensions within these ranges, or with any of numerous other dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 18 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowery et al. (5,364,399) in view of Studer et al. (6,146,383).

Lowery et al. disclose the claimed invention except for the removable head. Studer et al. disclose a similar fastener 1 having a removable head, e.g. 9 in Figs. 1 and 2 or 10 in Figs. 3 and 4, to allow the device to be assembled after implantation of the

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bone screw and to facilitate optimal positioning and seating of the screw (see Figs. 1-4 and col. 1, lines 35-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the fixation device of Lowery et al. with a fastener having a removable head, in view of Studer et al., in order to allow the device to be assembled after implantation of the bone screw and to facilitate optimal positioning and seating of the screw.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lowery et al. (5,364,399).

Lowery discloses the claimed invention except for the inner surface comprising a deformable material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the inner surface of a deformable material, or of any of numerous known materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lowery et al. (5,364,399).

Lowery et al. disclose the claimed invention except that they disclose using a screw instead of a nut as the clamping member. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the clamping member of Lowery et al. as a nut (on a threaded stud) instead of a screw (in a threaded hole), as such would merely constitute substitution of functionally equivalent fastening means known in the art. Furthermore, it is noted that doing so would also be obvious

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because it merely involves the reversal of essential working parts of a device, which has been held to involve only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Allowable Subject Matter

Claims 43-61 are allowed.

Response to Arguments

Applicant's arguments have been considered but are moot in view of new ground(s) of rejection set forth above.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.

DC

D. Comstock
12 July 2004


KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700